

Serial No.: 10/807,991
Docket No.: ECV-5510CON
Amendment dated May 12, 2005
Responsive to Office Action of December 13, 2004

REMARKS

Reconsideration of the application in view of the above claim amendments and the following remarks is respectfully requested.

Please note the attached Information Disclosure Statement.

5 Claims 1-22 were pending prior to the present Office Action. Claims 1-22 have been canceled, and claim 23-40 have been added. Therefore, claims 23-40 remain pending.

Claim 22 stood rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, the trade name "Denacol" has been removed from the claims.

10 Claims 1-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kim, et al. (USPN 5,697,972) and McIlroy, et al. (USPN 6,093,930). As indicated above, claims 1-22 have been canceled in favor of new claims 23-40. Therefore, the rejections will be discussed relative to the new claims.

15 The new claims provide methods for chemically treating and oxidizing a biological tissue that include either fixing the biological tissue by contacting it with a solution including a chemical fixative agent and an oxidizing chemical and heating the solution to between 45-55°C, or fixing the biological tissue by contacting it with a solution including a chemical fixative agent and heating the solution to between 45-55°C, and then contacting the biological tissue with an oxidizing chemical. Applicants respectfully assert that these claims are not disclosed or suggested by either of the cited references, alone or in combination.

20 Kim, et al. disclose a method for the preparation of bioprosthetic heart valves resistant to calcification that involves covalently binding an anionic hydrophilic polymer derivative of sulfonated polyethylene oxide to the tissue by means of chemically modified procedures. Kim, et al. teach modifying the bioprosthetic valve by oxidation with sodium metaperiodate, neutralization with ethylene glycol, and fixation with glutaraldehyde. The oxidation and fixation procedures are 25 separated by an intermediate neutralization step. In every specific example given, the tissue is fixed in a glutaraldehyde solution for a week at 4°C. Nowhere do Kim, et al. suggest fixing the tissue any other way, and in particular at higher temperatures (e.g., 45-55°C). With regard to claim 23, Kim, et al. teach separate fixing and oxidizing steps.

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McIlroy, et al. disclose a method of tanning biomaterial to increase calcification resistance. The method comprises tanning the tissue by any method except by oxidation (see, e.g., Abstract and column 5, lines 10-12), and then at a different time tanning the tissue by various oxidative fixation methods, especially by photo oxidation. McIlroy, et al. do not suggest fixing the tissue at 5 any temperature above 37°C (see top of column 6). With regard to claim 23, McIlroy, et al. explicitly teach away from simultaneously fixing and oxidizing the tissue.

Applicants assert that claims 23 and 32 are not obvious in view of the combination of Kim, et al., and McIlroy, et al. because neither suggests combining a fixation step at the claimed temperatures combined, simultaneously or at a different time, with an oxidation step. Kim, et al. 10 specifically sets forth a temperature of 4°C, and McIlroy, et al. discloses test samples made at 4°C, room temperature, and 37°C. There is no discussion in McIlroy, et al. of increasing the temperature above 37° C., and no discussion of the impact of fixation of these different temperatures. Therefore, there is no motivation provided to increase the fixation temperature.

The present claims are different from the disclosures of the prior art alone, or in 15 combination, not merely because there are "differences in concentration or temperature." Instead, the invention as presently claimed provides a novel and nonobvious combination of process steps that is different in kind from those of the prior art. Moreover, the Examiner has not identified (and indeed, there is none to identify) any evidence that the fixation temperature is recognized in either Kim, et al. or McIlroy, et al. as a "result effective variable." As such, modifying the fixation 20 temperature of either of these two references would not be suggested, let alone routine, to one of skill in the art.

Applicants also wish to point out that the dependent claims provide further process parameters that are not disclosed or suggested in either Kim, et al. or McIlroy, et al. To cite just one example, claims 31 and 40 specify that the time period for fixation at a temperature of 25 between 45-50°C is between 7 and 14 days. Kim, et al. only discloses fixation at 4°C, even if it is for a week, and McIlroy, et al. only discloses fixation of test samples for 24 hours at various temperatures up to 37°C. The combination of an elevated fixation temperature and extended time is simply not suggested by these two references alone, or in combination.

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Fees Due to File This Amendment

Prior to the pending Office Action, a fee was paid for the original 22 claims, with 1 of them being independent. The above claim changes have not resulted in any new claim fees.

Applicants hereby petition for an extension of time of two (2) months to respond to the Office
5 Action dated December 13, 2004. Please charge Deposit Account No. 50-1225 the fee of \$450
pursuant to 37 C.F.R. §1.17(a)(2) (ECV-5510CON).

Conclusion

Accordingly, in view of the above amendments and remarks, it is submitted that this
10 application is now ready for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (773) 857-7634.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16
15 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225 (ECV-5510CON).

Respectfully submitted,



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